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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,961	06/22/2001	Hassan Jomaa	JOMAA-4	9957

25889 7590 12/24/2002

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EXAMINER

LAMBKIN, DEBORAH C

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 12/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,961

Applicant(s)

JOMAA, HASSAN

Examiner

Deborah C Lambkin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 12-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Election/Restrictions

Applicant's election with traverse of Group 1, species amino-hydroxybutylidene-bisphosphonate, in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the search and examination would necessarily include both groups and hence not present an undue burden. This is not found persuasive because truth in fact, a different and separate search and examination would have to be performed for each of the two groups since they refer to structurally dissimilar compounds which are not obvious variants and hence presents an undue burden to the examiner to search and examine both groups in a single application. Furthermore, in the same token that applicant finds filing multiple applications (just one more) does not serve to promote the public interest, the examiner finds the same if applicant was allowed to patent multiple inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Consequently, the claims were examined solely to the extent in which they read on the elected subject matter.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "Use" by itself does not fall into any of the five classes of statutory subject matter.

In the interest of time, it is being assumed that the instant claims are directed to
“ A method for preventing or treating diseases caused by parasites, viruses etc.,
comprising administering to a patient in need thereof an effective amount of
bisphosphonic acids of the formula....for the inactivation of ...T-cells....” or similar
claim language.

Applicant is requested to rewrite the claims to conform to conventional US format
for method of use type claims. Accordingly, action on the merits is based on the
exemplified format above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, because the
specification, while being enabling for the inactivation of gamma/delta T cells, does not
reasonably provide enablement for the “prevention” of all and any viral, bacterial and
fungal infections. The specification does not enable any person skilled in the art to
which it pertains, or with which it is most nearly connected, to use the invention
commensurate in scope with these claims. It is not seen how applicant can prevent viral
infections such as the common cold or moreover prevent any infection from the

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enablement presented in the instant specification. The skilled artisan would have to practice unduly to prevent infections as claimed. An analysis of the In re Wands (USPQ 8, 2d, 1400) factors for enablement indicates that in the instant case the enablement is not commensurate in scope to the claims.

Claims 12-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The prior art (See Kunzmann et al (1997), Immunobiology, Vol. 197, p.221) teaches that bisphosphonates activate gamma/delta T cells. This is opposite to applicant's claims that bisphosphonates inactivate the same gamma/delta cells. An explanation is requested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of "such as" and "in particular" are indefinite claim language.

Claims 12-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear exactly what applicant is claiming because the claims recite " use of ", furthermore, the required action step for a method of use is absent, and finally the statement, " ...or compounds which, on administration, form the compounds to be administered as metabolites or breakdown products, for the production of pharmaceutical preparations..." is highly confusing. It is not clear what are the "or compounds, metabolites or breakdown products" and what is actually administered.

Applicant should use the claim language suggested above by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12,13,14,16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Gertz et al (US 5,270,365).

Gertz et al teach the bisphosphonates, ABP and its salts or alendronate, to be useful for treating periodontal disease caused by bacteria which reads on the instant broad use and broad bisphosphonates (col,3, lines 17-25; col.4, lines 1-68).

Claims 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Pauls et al (US 5,563,128).

Pauls et al teach phosphonate derivatives which are also useful in treating fungal infections which read on the instant broad compounds such as esters, salts of esters or

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compounds, metabolites or breakdown products and anti-fungal use (col. 24, lines 60-68; cols. 27-32).

Claims 12-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramamurthy et al (US 6,114,316).

Ramamurthy et al teaches a combination of bisphosphonate and tetracycline for treating microbial, viral and fungal proteinases mediated conditions which reads on the instant open language and combination treatment (see pages 7&8 of the instant specification).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byington et al (1997), Experimental Parasitology, 87, 194-202) in view of Gertz et al, Pauls et al and Ramamurthy et al.

Byington et al teach that bisphosphonates such as etidronate, pamidronate and alendronate can be useful in treating certain parasitic infections such as intestinal amebiasis, giardiasis or vaginal trichomoniasis.

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Gertz et al. Pauls et al and Ramamurthy et al have been discussed supra and actually show collectively that a variety of bisphosphonates are useful in treating viral, bacterial and fungal infections.

Consequently, it would have been prima facie obvious to one having ordinary skill in the art at the time the application was filed to use known bisphosphonates for treating viral, bacterial or fungal infections because a sufficient number of bisphosphonates have already demonstrated such activity wherein there is a reasonable expectation that similar bisphosphonates would have possess the same or similar activity, absent some unobvious or unexpected results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah C. Lambkin whose telephone number is 703-308-4522.

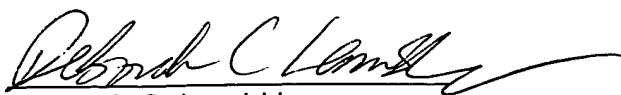
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537. The fax phone number for the organization where this application or proceeding is assigned is 703-308-7922.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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A handwritten signature in black ink, reading "Deborah C. Lambkin", with a long horizontal flourish extending to the right.

Deborah C. Lambkin

Primary Patent Examiner

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DEBORAH C. LAMBKIN
PRIMARY EXAMINER